**Rep. Joseph R. Pitts**
**Opening Statement**
**Energy and Commerce Subcommittee on Health**
**Hearing on "Reauthorization of Animal Drug User Fees: ADUFA and AGDUFA"**
**April 9, 2013**

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

Today's hearing focuses on the reauthorization of two successful programs – the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA).

In 2003, ADUFA I was authorized to help the Food and Drug Administration's (FDA) review of animal drugs.

Similar to the Prescription Drug User Fee for human drugs, under ADUFA, FDA collected funds to help expedite the new animal drug approval process, reduce the application backlog and improve communications with drug sponsors.

The program was authorized for five years, and Congress renewed the program for an additional 5 years in ADUFA II in 2008.

In FY2012, FDA completed 747 ADUFA reviews, and, according to FDA, the agency has exceeded all performance goals outlined in ADUFA I and II.

However, absent Congressional action, FDA's ability to collect these user fees will expire September 30, 2013.

FDA and industry have negotiated an agreement regarding the size and scope of ADUFA III, which would extend the program through FY2018, and these recommendations were delivered to the Committee in February.

Under the negotiated proposal, industry would pay approximately $23.6 million in FY2014, and similar amounts, adjusted for inflation, for FYs 2015-2018.

Twenty percent of this total would come from application fees, 27% from product fees, 27% from sponsor fees, and 26% from establishment fees.

The ADUFA III proposal also includes an annual offset adjustment based on any collection shortfall in previous years.

AGDUFA I, ADUFA's generic cousin, was first authorized in 2008 for 5 years, in order to improve the review of abbreviated new animal drug applications (ANADAS), eliminate application backlogs, and reduce review times.

To date, according to FDA, the agency has exceeded all performance goals but one from AGDUFA I.

This program also expires September 30, 2013 unless it is reauthorized, and FDA and industry have negotiated an agreement for AGDUFA II.

Under the proposed AGDUFA II agreement, industry would pay:

- $7,328,000 in FY2014 (which allows for the hiring of 22 FTEs and includes a one-time cost of $850,000 for information technology);
- $6,944,000 in FY2015;
- $7,429,000 in FY2016;
- $7,936,000 in FY2017; and
- $8,467,000 in FY2018.

These fees would be paid through application fees (25% of the total), product fees (37.5%), and sponsor fees (also 37.5% of the total).

The legislation to reauthorize ADUFA III was introduced today by Rep. John Shimkus, and the AGDUFA II reauthorization, sponsored by Rep. Cory Gardner, also was introduced today.

I want to welcome all of our witnesses and thank them for being here today. I look forward to your testimony.

Thank you. At this time, I would like to request unanimous consent for Congressman Gardner to participate in the subcommittee hearing. Without objection so ordered. I now yield the remainder of my time to Rep. Gardner.